

REMARKS

Claims 1, 3-18, 20-26 and 28-34 were pending in the application. Claims 1, 3, 18, and 23 are amended. Claims 21 and 22 are canceled and claims 35-38 are added. Accordingly, claims 1, 3-18, 20, 23-26 and 28-38 are currently under consideration. Support for the new claims 35-38 can be found throughout the application as originally filed and, *inter alia*, at paragraph 49 of the specification. Accordingly, the above amendments do not introduce any new matter.

With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and moreover has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application

Rejections Under 35 U.S.C. 112

Claims 1, 3-17, 20, 23-26, and 28-34 stand rejected under 35 U.S.C. 112, first paragraph as allegedly not being enabling for the claimed methods. In view of the presently submitted amendment, the rejection is believed to be moot. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. 103

In order to establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

Claim 1 stands rejected as allegedly unpatentable over Campbell (US H1398) in view of Yamane (USP 4,876,335) under 35 U.S.C. 103(a). This rejection is believed to be moot in view of the presently submitted claims. Claims 3-5, 7-9, 11-13, 23-26, 28, and 30-31 are rejected under 35 U.S.C. 103 as allegedly being unpatentable over Campbell in view of Gold. This rejection is respectfully traversed. The rejection alleges that it would be obvious to combine the nucleic acid amplification reaction of Campbell with a nucleic acid bound to a carrier macromolecule disclosed by Gold (Office Action dated 6/14/06, p. 8, lines 11-16). Gold discloses a method for preparing a therapeutic or diagnostic complex, which complex contains a nucleic acid ligand and a Non-Immunogenic, High Molecular Weight Compound (Col. 5, lines 15-20). But Gold completely fails to disclose hybridizing such a complex to a template nucleic acid, and using it to extend the primer to form an extended primer, as is presently claimed. Gold never discloses or suggests the complexes would be useful or even usable in this context. Instead, Gold discloses the Non-Immunogenic High Molecular Weight Compounds as useful as therapeutic and diagnostic agents (Col. 5, lines 15-16), and as useful for enhancing the cellular uptake of the nucleic acid ligands (Col. 5, lines 30-32), which purposes find no use in the claimed assay.

The rejection alleges that the person of ordinary skill would be motivated to replace the fluorescent label of Campbell with the nucleic acid-carrier macromolecule of Gold, because it is allegedly a simple replacement of one label for another (Office Action mailed 6/14/06, p. 8, lines 14-21). But such a replacement would eliminate the "reporter molecule" from the assay of Campbell, which reporter molecule is a necessary part of the Campbell assay. Therefore, in order to combine and modify Campbell in view of Gold to arrive at the invention of claims 3-5, 7-9, 11-13, 23-26, 28, and 30-31, as alleged by the Examiner, the combination or modification would eliminate the signal generating fluorescent label and render Campbell's invention inoperable. Accordingly, there is no suggestion or motivation to make the proposed combination or modification. See e.g., MPEP 2143.01 V. citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification).

In addition, such a replacement would also have unpredictable consequences for the amplification given the large size difference between the fluorescent label of Campbell and the macromolecule of Gold, and especially since the macromolecule of Gold is completely untested in nucleic acid amplification assays. And no advantage is suggested by the references or the knowledge of one of ordinary skill that would apparently be obtained by doing so.

Thus, no motivation is found to utilize the complex of Gold as a primer in the assay of Campbell. Such a combination can be made only by using impermissible hindsight, which of course is not permitted by the patent laws. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 381 F.3d 1371 (Fed. Cir. 2004) (“...the suggestion to combine references must not be derived by hindsight from knowledge of the invention itself”). Therefore, the cited claims are not obvious over the combination of Campbell and Gold.

A number of additional rejections under 35 U.S.C. 103(a) were included over certain dependent claims. These rejections will be addressed as a group. The rejections include combinations of:

Campbell, Gold, and further in view of Mehta (claim 6);

Campbell, Gold, and further in view of Landgren (claims 10, 14-17, 29, 32-33);

Campbell, Gold, and Landegren, and further in view of Barany (claim 20);

Campbell in view of Gold, and further in view of Yamane (claim 34);

None of the additional references cited in combination with Campbell and Gold supply the elements and motivation missing from both Campbell and Gold. Therefore, none of the claims cited in these rejections are rendered unpatentable in view of these further references.

Claim 18 stands rejected as allegedly being unpatentable under 35 U.S.C. 103(a) over Steeg in view of Matteucci. It is believed that the amendment to claim 18 renders this rejection moot.

CONCLUSION

In view of the above, the pending claims are believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims, and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 577212000101.

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